

CERTIFICATE OF ELECTRONIC SUBMISSION

DATE OF FILING January 5, 2007

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
An, et al.

Serial No.: 09/974,546

Filed: October 10, 2001

For: BIOMARKERS AND TARGETS FOR
DIAGNOSIS, PROGNOSIS AND
MANAGEMENT OF PROSTATE,
BREAST AND BLADDER CANCER

Group Art Unit: 1643

Examiner: Rawlings, Stephen L.

Atty. Dkt. No.: UROC:018USD2

SUPPLEMENTAL BRIEF ON APPEAL

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SUPPLEMENTAL BRIEF ON APPEAL

MS Appeal Briefs

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit this Supplemental Appeal Brief pursuant to a Notification of Non-Compliant Appeal Brief dated December 6, 2006.

No fees are believed to be due in connection with the this filing; however, should any additional fees become due under 37 C.F.R. §§ 1.16 to 1.21 for any reason relating to the enclosed materials, or should an overpayment be made, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/UROC:018USD2.

I. REAL PARTY IN INTEREST

The real parties in interest are Urocor, Inc. of Oklahoma City, Oklahoma, the assignee, and LabCorp of America, headquartered in Burlington, North Carolina, which purchased Dianon Systems, Inc., for which Urocor was the predecessor.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF THE CLAIMS

Claims 78-94 were originally filed in a Preliminary Amendment on October 10, 2001, while claims 1-77 of the parent application, Serial No. 09/097,199 (now U.S. Patent No. 6,218,529), were canceled.

In a Response to Restriction Requirement dated April 20, 2004, Appellants elected with traverse to prosecute the invention of Group XIX, claims 78-94, drawn to a method for treating cancer comprising administering an agent that inhibits a peptide or polypeptide encoded by SEQ ID NO: 83 or a fragment thereof. In a Response to Notice of Non-Compliant Amendment dated August 16, 2004, Appellants elected the species of invention wherein said cancer is prostate cancer. In an Office Action dated November 22, 2004, Groups XIX and XX (that is, a method for treating cancer comprising administering an agent that inhibits a peptide or polypeptide encoded by SEQ ID NO: 85 or a fragment thereof) were rejoined. Further, in this same Action, the requirement to elect a species of the invention from bladder, breast and prostate cancer was withdrawn.

In a Response to Office Action dated April 21, 2005, claims 78, 83, 86, 87 and 92 were amended and claim 85 was canceled.

Claims 78-84 and 86-94 were pending and rejected in the final office action dated November 10, 2005. Thus, claims 78-84 and 86-94 are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments have been filed since the final office action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention concerns generally concerns methods treating a patient with breast cancer, bladder cancer or prostate cancer comprising administering to the patient an effective amount of an agent that binds to a peptide or polypeptide encoded by SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:83 or SEQ ID NO:85, or a fragment thereof, such as described by claim 78. Specification at least at page 11, lines 6-17; page 13, lines 1-3; page 21, lines 24-26; page 44, lines 20-27; page 52, lines 12-23; page 54, lines 13-18 and page 117, lines 4-12. The present invention also generally concerns methods of treating a breast cancer, bladder cancer or prostate cancer cell comprising administering to the cell an effective amount of an agent that binds to a peptide or polypeptide encoded by SEQ ID NO:3, SEQ ID NO:83 or SEQ ID NO:85, or a fragment thereof, as described by claim 87. Specification at least at *id.* and page 13, lines 4-8 and 17-20.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- Claims 78-82, 86-91 and 94 have been rejected as lacking adequate written description under 35 U.S.C. § 112, first paragraph.

- Claims 78-84 and 86-94 have been rejected as lacking enablement under 35 U.S.C. § 112, first paragraph.
- Claims 78-82, 86-91 and 94 are rejected as being indefinite under 35 U.S.C. § 112, second paragraph.

VII. ARGUMENT

A. Substantial Evidence Required To Uphold Examiner's Position

Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act, 5 U.S.C. § 706(A), (E), 1994. *Dickinson v. Zurko*, 527 U.S. 150, 158 (1999). Moreover, the Federal Circuit has held that findings of fact by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record. *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000). In *In re Gartside*, the Federal Circuit stated that "the 'substantial evidence' standard asks whether a reasonable fact finder could have arrived at the agency's decision." *Id.* at 1312.

Accordingly, it necessarily follows that an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences.

B. Claims 78-82, 86-91 and 94 Are Adequately Described

Claims 78-82, 86-91 and 94 are rejected under the first paragraph of 35 U.S.C. § 112 as lacking adequate written description. The Action contends that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed

invention. More specifically, the Action states that the genus of “agents” recited in the claims includes structurally and functionally disparate molecules including, for example, naked antibodies, that specifically bind to the polypeptide and inhibit its activity or function, such that treatment of cancer cells with the antibody provides therapeutic benefit. The Action then contends that there is no language in the specification that adequately describes the genus of antibodies that bind a polypeptide of the present invention and inhibit its activity or function, so as to provide therapeutic benefit. To support this contention, the Action discusses the alleged lack of description regarding the activities of the polypeptides of the present invention, such that agents of the present invention could not inhibit these unknown activities. Appellants respectfully traverse this rejection.

“The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required ‘to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.’” *Moba v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003) (citing *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003)). An accepted standard for the written description requirement is: “Although the applicant does not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562-1563 (Fed. Cir. 1991). Written description is met if “the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” *Lampi*, 228 F.3d 1365, 1378 (Fed. Cir. 2000). Furthermore, the written description requirement of 35 U.S.C. § 112, first paragraph, requires that the specification “considered as a whole” describes

the invention. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000). Appellants contend that the entire specification conveys to the skilled artisan that the methods recited in claims 78-82, 86-91 and 94 were contemplated as part of the invention.

Claims 78 and 87, the independent claims from which the remaining rejected claims depend, recite the following: “A method of treating a [patient/cell] ... comprising administering ... an effective amount of an agent that binds to a peptide or polypeptide encoded by....” (emphasis added). These claims therefore are directed to agents that bind to certain peptides and/or polypeptides. Support for these claims can be found in the specification. *See, e.g.*, page 11, lines 6-17; page 13, lines 1-3; page 44, lines 20-27; page 52, lines 12-23; page 54, lines 13-18 and page 117, lines 4-12.

For example, the specification provides examples of agents that bind to the polypeptides of the invention. Described in the specification is an antibody that was made to UC 28 (encoded by the nucleotide sequence of SEQ ID NOs: 3, 83 and 85). On page 117, lines 4 through 12 state:

A first generation polyclonal antibody has been produced in rabbits using a KLH conjugated synthetic peptide (21 amino acids). The peptide, of sequence listed below, was chosen for antigenicity by a computer software program (DNASTARTM, Madison, WI).

RKKEKVKRSQKATEFIDYSIE SEQ ID NO:56

The synthetic peptide was conjugated to KLH by standard techniques and injected into two rabbits, with bleeding started at ten weeks. The antibody was peptide affinity purified and then tested in prostate cancer cell lines, and breast and prostate cancer tissue, confirming the localization of the UC 28 protein to epithelial cells, mainly on the cell membrane.

Appellants are prepared to deposit this antibody if this is deemed necessary to satisfy the written description requirement.

As an additional example, the specification recites, “The invention comprises methods of treating individuals with prostate, bladder or breast cancer by providing effective amounts of antibodies and/or antisense DNA molecules [*i.e.*, agents] which bind to the products of the above mentioned isolated nucleic acids.” Page 13, lines 1-3. Indeed, the Action concedes that agents of the present invention possess a “common ability to bind to” certain polypeptides of the present invention. The Action, page 9.

Thus, written description is provided for a species of the claimed agents, and it would be very clear to one of skill in the art that the inventors were in possession of the invention at the time of filing.

The Action further states that certain members of the genus of claimed agents are classified as inhibitors of certain peptides and polypeptides of the present invention, but that no activity has been identified for these peptides and polypeptides; as such, the Action concludes, one of ordinary skill in the art could not conclude that the Appellants were in possession of the claimed invention at the time it was filed because an inhibitor cannot be described if the activity it is allegedly inhibiting is not described. It appears that the entirety of the Action’s rejection is therefore based on the contention that all agents must be inhibitors. Contrary to the Action’s assertions, however, the rejected claims do not recite that all of the claimed agents must “inhibit” certain peptides and/or polypeptides: the claims instead state, as described above, that the agents must “bind to” certain peptides and polypeptides. The Action’s emphasis on the alleged lack of written description with respect to inhibitors of certain peptides and polypeptides of the present invention is therefore misplaced, and cannot be used to support the written description rejection.

According to the Federal Circuit, “[i]t is well-established that a patent applicant is entitled to claim his invention generically, when he describes it sufficiently to meet the

requirements of section 112.” *Amgen v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991); *see also Utter v. Hiraga*, 856 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988) (“A specification may, within the meaning of 35 U.S.C. § 112, paragraph 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.”) As indicated above, the specification provides sufficient written description to convey to one of ordinary skill in the art that the Appellants had possession of a genus of agents that bind to certain peptides and polypeptides of the present invention.

Claims 79-82 and 86 depend from claim 78, and claims 88-91 and 94 depend from claim 87: each of these dependent claims is similarly supported by the specification and claims as originally filed. *See, e.g.*, originally-filed claims 79-82, 86-91 and 94. Consequently, each of the dependent claims fulfill the written description requirements as well.

C. Claims 78-84 and 86-94 Are Enabled

The Action maintains a rejection of claims 78-84 and 86-94 under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably enable the scope of the present claims. Applicants respectfully traverse.

The general standard for enablement under § 112, first paragraph has been addressed in the case law repeatedly. For example, in *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993), the court stated that an enabling specification teaches those skilled in the art how to make and use the claimed invention in its full scope without "undue experimentation." *Wright*, 999 F.2d at 1560. It is well-settled patent law that the first paragraph of § 112 requires nothing more than objective enablement. *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). This objective enablement may be provided through broad terminology or illustrative examples. *Id.* As long as the specification discloses at least one method for making

and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(1) The Action's Arguments Based on All Agents as Inhibitors Cannot Support an Enablement Rejection

In one aspect, the Action relies on the argument presented in the written description rejection discussed above, wherein the genus of claimed agents includes inhibitors but that the function or activity of the claimed sequences is unknown—thus, the Action continues, a skilled artisan would have to perform undue experimentation to first determine such function or activity, then determine if that function or activity is related to cancer, and then design or discover an inhibitor of that function or activity. As noted above, the term “inhibits” does not appear in the present claims, but only agents that “bind to” peptides and/or polypeptides encoded by the claimed sequences. Because the present claims do not require that the agents act as inhibitors, the Action’s argument cannot be used to support an enablement rejection. Furthermore, and without conceding that any inhibitors of the present invention are not enabled, “It is not a function of the claims to specifically exclude either possible inoperative substances...” *In re Dinh-Nguyen and Stenhagen*, 492 F.2d 856 (CCPA 1974); *see also In re Hradcovsky*, 214 USPQ 554 (PTO Bd. App. 1982); *Atlas Powder Co. v. E. I. du Pont de Nemours & Co.*, 588 F.Supp. 1455 (Tex. 1983).

As discussed above, the specification further provides an example of a polyclonal antibody that binds to a polypeptide (UC 28) encoded by a nucleotide sequence (SEQ ID NOs: 3, 83 and 85) of the present invention. Page 117, lines 4-12. As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112

is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. § 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 954 (1987).

Finally, it is pointed out that effective targeting of cancer cells with a *binding agent* of the invention does not require determining the function or activity of the polypeptide, or whether the function of the polypeptide correlates with the onset of cancer, or the discovery of an inhibitor of that function activity. The Action does not assert that agents that *bind to* peptides or polypeptides of the present invention are not enabled. As such, the present claims are enabled.

(2) *The Specification Does Not Fail to Teach That UC 28 Is Expressed on the Membrane of Cancer Cells*

In another aspect, the Action asserts that because the specification fails to teach whether the polypeptide encoded by SEQ ID NOs: 3, 83 and 85, designated therein as UC 28, is expressed at the surface of cells, the specification therefore fails to teach whether any antibody or other inhibitor can specifically bind to and exert any inhibitory effect on those cells. Instead, the Action asserts that An *et al.* (*Cancer Res.* **60**:7014-7020, 2000, Exhibit A) provides factual evidence that UC 28 (called “UROC 28” in An *et al.*) is not expressed at the surface of cells.

In response, Appellants note that studies described in the specification on page 117, lines 10-14 indicated that the peptide encoded by SEQ ID NOs: 3, 83 and 85 was found on the cell membrane. As further evidence, Appellants submitted a declaration of Dr. Veltri (Exhibit B) in the Response to Office Action dated April 21, 2005. The declaration was made with respect to a co-pending application but is believed to be relevant here as proof that UC 28 is expressed on the membrane of cancer cells. Declaration, ¶¶ 8, 9. Therefore, one of skill in the art would expect

for an agent that binds to a polypeptide encoded by SEQ ID NOs: 3, 83 and 85 to target cancer cells that overexpress these proteins.

The Action reasons that based on the following statement found on page 7017, col. 2 of An *et al.*, localization of UC 28 to the cell membrane must not have been remarkable: “UROC28 protein was localized primarily in the cytoplasm of prostate and breast cancer glandular epithelial cells.” However, this statement does not make the distinction that the protein was in the cytoplasm *as opposed* to the membrane. It is perfectly consistent that the protein be in the cytoplasm but also membrane-bound—a point supported by the next statement in the An reference, which refers to nuclear localization. Page 7017, col. 2.

Furthermore, Dr. Veltri identifies amino acids 34-50 of SEQ ID NO:2 of UC 28 as a putative transmembrane domain. Declaration, ¶ 6. As such, a portion(s) of UC 28 putatively is exposed to the cell surface. Dr. Veltri’s statement is supported by the abstract of the An *et al.* reference, which states: “Bioinformation analyses suggest that there is a possible transmembrane domain from amino acids aa34 to aa50....” This statement is made in a peer-reviewed article in a scientific journal, and furthermore, it adds support to the argument that the authors of this reference did not intend to distinguish cytoplasmic localization from membrane localization. Therefore, the basis for this ground of the rejection is without merit. The Action does not provide a reasonable basis for challenging the assertion in the specification that UC 28 localizes to the cell membrane, nor for challenging the assertion that at least a portion of UC 28 is expressed on the outside of the cell.

The Action tries to support the enablement rejection by asserting uncertainty with respect to this “putative” domain in combination with An *et al.*’s reference to UC 28’s localization “primarily” in the cytoplasm. While the presence of the transmembrane is putative, Appellants

note that in examining a patent application, the PTO is required to assume that the specification complies with the enablement provisions of Section 112 unless it has “acceptable evidence or reasoning” to suggest otherwise. *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-370 (CCPA 1971). As discussed, localization of UC 28 “primarily” in the cytoplasm does not exclude its localization to the membrane. The presence of a putative transmembrane domain, in combination with Dr. Veltri’s statement that UC 28 is localized to the cell membrane, together establish that UC 28 is localized to the cell membrane, thereby overcoming the enablement rejection.

(3) *The Specification Is Enabling for the Design of Chemotherapeutic Agents*

With respect to claims 84 and 93, the Action asserts that the degree of unpredictability and extreme complexity in the art of anticancer drug discovery is such that a chemotherapeutic agent of the present invention cannot be recognized or made by routine experimentation alone. Appellants assert that use of anticancer agents of the invention does not require undue experimentation. For example, in certain embodiments of the invention, binding agents may be conjugated to radionuclides or to chemotherapeutic agents. Use of radionuclides and chemotherapeutic agents is well known in the art, and both radionuclides and chemotherapeutics are widely used in the treatment of cancer. Conjugation of radionuclides and/or chemotherapeutics to agents of the invention may increase their efficacy or reduce toxicity to healthy tissue. Thus, there would be no requirement for the kind of protracted analyses that the Action indicates would be necessary in order to practice the invention.

Moreover, as has been determined by the courts, the scope of the enablement must only bear a “reasonable correlation” to the scope of the claims. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Even if experiments are necessary, a considerable amount of

routine experimentation is permissible; the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Wands*, 858 F.2d 737, 8 USPQ2d 1404 (Fed. Cir. 1985); *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom. Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Thus, even if extensive experimentation is necessary to identify chemotherapeutic agents of the present invention, such experimentation does not mean the specification fails to enable the present claims.

In fact, binding agents that target cancer cells, such as those of the current invention have been used in clinical trials. Carroll, 2004 (Exhibit C) reports use of a yttrium-90 labeled monoclonal antibody targets a membrane protein on prostate cancer cells. Results from this study indicated that the antibodies labeled with the radionuclide had "[a]cceptable toxicity, excellent targeting of known sites of PC metastases, and biologic activity" in patients. Thus, Carroll indicates that agents for the treatment of cancer such as those of the invention are known to be effective for cancer therapy, and even for the treatment of solid tumors. As detailed above the specification provides enabling written description that would allow a person of normal skill in the art to apply the invention for the treatment of cancer without undue experimentation.

(4) *The Specification Demonstrates a Correlation Between the Level of mRNA Expression and the Level of Protein Expression in Cancer Cells*

The Action further indicates that the specification teaches that mRNAs corresponding to the sequences of the invention are overexpressed in cancer cells; however, the Action then states

that it does not teach that the polypeptide encoded by these RNAs are overexpressed *per se* and therefore, a method for treating cancer by targeting cells overexpressing these polypeptides lacks enablement. Appellants respectfully traverse, because it is demonstrated in the specification that, for instance, UC 28 mRNA is overexpressed in breast cancer cells (FIG. 15), 4 out of 5 bladder cancer cell lines (FIG. 16) and is hormone inducible in prostate in a prostate cancer cell line (FIG. 17). The Action concedes that the specification teaches overexpression in breast and prostate cancer cells. The Action, page 21. Additionally, U.S. Patent Application Serial No. 08/692,787 (now U.S. Patent No. 5,886,284), incorporated by reference by the present specification at page 1, lines 6-8, describes the overexpression of UC 28 in prostate cells (*see, e.g.,* Figure 3). While overexpression of the mRNAs in one cell line might result from random mutation during cancer development, overexpression in a wide range of cells would suggest to one of skill in the art that overexpression of the polypeptide was in fact advantageous to the cancer cell. Thus, the demonstration that a variety of cells overexpress the sequences of the invention implicitly indicates corresponding polypeptide overexpression.

Therefore, it is clear to one of skill in the art that the specification does teach that UC 28 protein is overexpressed in the cancer cells recited in the claims, thus enabling a method of treating cancer that targets cells expressing UC 28.

For the foregoing reasons, Appellants respectfully request this rejection be withdrawn.

D. Claims 78-82, 86-91 and 94 Are Not Indefinite

The Action rejects claims 78-82, 86-91 and 94 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Action contends that the phrase “effective amount” is indefinite for allegedly failing to state the function that is to be achieved. More

specifically, the Action states that it cannot be determined if the claim requires the “effective amount” of an agent to be sufficient to effectively inhibit the polypeptide, or to effectively treat cancer in a patient, or both. Appellants respectfully traverse.

The standard of precision regarding indefiniteness is “whether one skilled in the art would understand the bounds of the claim when read in light of the specification.... If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.” *Miles Laboratory, Inc. v. Shandon Inc.*, 27 USPQ2d 112, 1126 (Fed. Cir. 1993). *See also Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 57 USPQ2d 1293 (Fed. Cir. 2001) and MPEP § 2173.02. When read in light of the specification, the phrase “effective amount” is definite and satisfies all of the requirements of 35 U.S.C. § 112, second paragraph.

The phrase “effective amount” is found in independent claims 78 and 87, which recite: “A method of treating [a patient with breast cancer, bladder cancer or prostate cancer/a breast cancer, bladder cancer or prostate cancer cell] comprising administering to the [patient/cell] an effective amount of an agent that binds to a peptide or polypeptide encoded by....” As discussed above, Appellants note that the claims do not recite the term “inhibit” with respect to administration of the claimed agents, but instead that “an effective amount of an agent that *binds to* a peptide or polypeptide” is administered (emphasis added). Thus, to the extent the Action’s argument is based upon any required inhibitory activity of the claimed agents, the argument cannot support an indefiniteness rejection.

The meaning of the phrase “effective amount” is described in the specification: “An effective amount of the therapeutic composition is determined based on the intended goal.” Specification, page 83, lines 29-30. It is clear to one of ordinary skill in the art that the goal of

the rejected claims is to treat either: (a) a patient with breast cancer, bladder cancer or prostate cancer, or (b) a breast cancer, bladder cancer or prostate cancer cell, such that the amount of the agent administered binds to a peptide or polypeptide encoded by a claimed sequence. Accordingly, an “effective amount” of an administered agent is one that results in treatment of a patient or cell via binding to a peptide or polypeptide encoded by a claimed sequence. Therefore, this phrase is not indefinite, and one of ordinary skill in the art would understand the meaning and use of this phrase in the claims when read in light of the specification.

Further, one of ordinary skill in the art would be able to determine from the specification what an effective amount is. For example, page 83, line 29 through page 84, line 11, give guidance to a skilled artisan as to how to determine an effective amount, including exemplary unit dosages that may be administered. Such descriptive support renders the claims not indefinite. *See, e.g., Ex part Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989) and MPEP § 2173.05(c).

The rejection of the phrase “effective amount” as being indefinite is therefore improper and should be withdrawn.

E. Conclusion

For the above-argued reasons, Appellants respectfully request that the rejection of claims 78-84 and 86-94 be reversed. Appellants have provided arguments that overcome the pending rejections. Appellants respectfully submit that the Examiner’s conclusion that the claims should be rejected is legally and factually unsupported. It is therefore again requested that the Board overturn the Examiner’s rejection.

Please date stamp and return the enclosed postcard to evidence receipt of this document.

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Date: January 5, 2007

Respectfully submitted,

A handwritten signature in black ink that reads "Tamara Kale". The script is cursive and fluid, with the first name "Tamara" and last name "Kale" clearly distinguishable.

Tamara A. Kale
Reg. No. 53,087
Attorney for Appellants

VIII. CLAIMS APPENDIX

78. A method of treating a patient with breast cancer, bladder cancer or prostate cancer comprising administering to the patient an effective amount of an agent that binds to a peptide or polypeptide encoded by SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:83 or SEQ ID NO:85, or a fragment thereof.

79. The method of claim 78, wherein the agent is an antibody.

80. The method of claim 79, wherein the antibody is specific to a polypeptide encoded by SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:16, SEQ ID NO:17, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:83 or SEQ ID NO:85 or a fragment thereof.

81. The method of claim 80, wherein the antibody is a monoclonal antibody.

82. The method of claim 80 wherein the antibody is a polyclonal antibody.

83. The method of claim 80, wherein the antibody is conjugated to a radionuclide.

84. The method of claim 80, wherein the antibody is linked to a chemotherapeutic agent.

86. The method of claim 78, wherein the agent binds to a polypeptide encoded by SEQ ID NO: 3, SEQ ID NO: 83 or SEQ ID NO: 85 or a fragment thereof.

87. A method of treating a breast cancer, bladder cancer or prostate cancer cell comprising administering to the cell an effective amount of an agent that binds to a peptide or polypeptide encoded by SEQ ID NO:3, SEQ ID NO:83 or SEQ ID NO:85, or a fragment thereof.

88. The method of claim 87, wherein the agent is an antibody.
89. The method of claim 88, wherein the antibody is specific to a polypeptide encoded by SEQ ID NO:3, SEQ ID NO:83 or SEQ ID NO:85 or a fragment thereof.
90. The method of claim 88, wherein the antibody is a monoclonal antibody.
91. The method of claim 88, wherein the antibody is a polyclonal antibody.
92. The method of claim 88, wherein the antibody is conjugated to a radionuclide.
93. The method of claim 88, wherein the antibody is linked to a chemotherapeutic agent.
94. The method of claim 87, wherein the cell is in a patient.

IX. EVIDENCE APPENDIX

Previously submitted.

X. RELATED PROCEEDINGS APPENDIX

[NONE]